

JAN 19 2007

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# A BILL FOR AN ACT

RELATING TO HEALTH.

**BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:**

1           SECTION 1. Chapter 324, Hawaii Revised Statutes, is  
2 amended by adding a new section to be appropriately designated  
3 and to read as follows:

4           "§324-       Adverse events; data collection and reporting.

5           (a) The department of health shall adopt rules under chapter 91  
6 that require the department to collect and analyze data on the  
7 number and type of adverse events that occur in health care  
8 facilities in the State.

9           As used in this section, "health care facility" includes  
10 "health care facility" and "organized ambulatory health care  
11 facility" as those terms are defined in section 323D-2.

12           As used in this section, "adverse event" includes any of  
13 the following:

14           (1) Surgical events, including the following:

15           (A) Surgery performed on a wrong body part that is  
16 inconsistent with the documented informed consent  
17 for that patient. A reportable event under this  
18 subparagraph does not include a situation



1 requiring prompt action that occurs in the course  
2 of surgery or a situation that is so urgent as to  
3 preclude obtaining informed consent;

4 (B) Surgery performed on the wrong patient;

5 (C) The wrong surgical procedure performed on a  
6 patient, which is a surgical procedure performed  
7 on a patient that is inconsistent with the  
8 documented informed consent for that patient. A  
9 reportable event under this subparagraph does not  
10 include a situation requiring prompt action that  
11 occurs in the course of surgery, or a situation  
12 that is so urgent as to preclude the obtaining of  
13 informed consent;

14 (D) Retention of a foreign object in a patient after  
15 surgery or other procedure, excluding objects  
16 intentionally implanted as part of a planned  
17 intervention and objects present prior to surgery  
18 that are intentionally retained; and

19 (E) Death during or up to twenty-four hours after  
20 induction of anesthesia after surgery of a  
21 normal, healthy patient who has no organic,  
22 physiologic, biochemical, or psychiatric



1 disturbance and for whom the pathologic processes  
2 for which the operation is to be performed are  
3 localized and do not entail a systemic  
4 disturbance.

5 (2) Product or device events, including the following:

6 (A) Patient death or serious disability associated  
7 with the use of a contaminated drug, device, or  
8 biologic provided by the health facility when the  
9 contamination is the result of generally  
10 detectable contaminants in the drug, device, or  
11 biologic, regardless of the source of the  
12 contamination or the product;

13 (B) Patient death or serious disability associated  
14 with the use or function of a device in patient  
15 care in which the device is used or functions  
16 other than as intended. For purposes of this  
17 subparagraph, "device" includes, but is not  
18 limited to, a catheter, drain, or other  
19 specialized tube, infusion pump, or ventilator;  
20 and

21 (C) Patient death or serious disability associated  
22 with intravascular air embolism that occurs while



1           being cared for in a facility, excluding deaths  
2           associated with neurosurgical procedures known to  
3           present a high risk of intravascular air  
4           embolism.

5       (3) Patient protection events, including the following:

6           (A) An infant discharged to the wrong person;

7           (B) Patient death or serious disability associated  
8           with patient disappearance for more than four  
9           hours, excluding events involving adults who have  
10           competency or decision-making capacity; and

11          (C) A patient suicide or attempted suicide resulting  
12           in serious disability while being cared for in a  
13           health facility due to patient actions after  
14           admission to the health facility, excluding  
15           deaths resulting from self-inflicted injuries  
16           that were the reason for admission to the health  
17           facility.

18       (4) Care management events, including the following:

19           (A) A patient death or serious disability associated  
20           with a medication error, including, but not  
21           limited to, an error involving the wrong drug,  
22           the wrong dose, the wrong patient, the wrong



1           time, the wrong rate, the wrong preparation, or  
2           the wrong route of administration, excluding  
3           reasonable differences in clinical judgment on  
4           drug selection and dose;

5           (B) A patient death or serious disability associated  
6           with a hemolytic reaction due to the  
7           administration of blood type-incompatible blood  
8           or blood products;

9           (C) Maternal death or serious disability associated  
10           with labor or delivery in a low-risk pregnancy  
11           while being cared for in a facility, including  
12           events that occur within forty-two days post  
13           delivery and excluding deaths from pulmonary or  
14           amniotic fluid embolism, acute fatty liver of  
15           pregnancy, or cardiomyopathy;

16           (D) Patient death or serious disability directly  
17           related to hypoglycemia, the onset of which  
18           occurs while the patient is being cared for in a  
19           health facility;

20           (E) Death or serious disability, including  
21           kernicterus, associated with failure to identify  
22           and treat hyperbilirubinemia in neonates during



1 the first twenty-eight days of life. For  
2 purposes of this subparagraph,  
3 "hyperbilirubinemia" means bilirubin levels  
4 greater than thirty milligrams per deciliter;

5 (F) A stage 3 or stage 4 ulcer, acquired after  
6 admission to a health facility, excluding  
7 progression from Stage 2 to Stage 3 if Stage 2  
8 was recognized upon admission; and

9 (G) A patient death or serious disability due to  
10 spinal manipulative therapy performed at the  
11 health facility.

12 (5) Environmental events, including the following:

13 (A) A patient death or serious disability associated  
14 with an electric shock while being cared for in a  
15 health facility, excluding events involving  
16 planned treatments, such as electric counter  
17 shock;

18 (B) Any incident in which a line designated for  
19 oxygen or other gas to be delivered to a patient  
20 contains the wrong gas or is contaminated by a  
21 toxic substance;



- 1            (C) A patient death or serious disability associated
- 2            with a burn incurred from any source while being
- 3            cared for in a health facility;
- 4            (D) A patient death associated with a fall while
- 5            being cared for in a health facility; and
- 6            (E) A patient death or serious disability associated
- 7            with the use of restraints or bedrails while
- 8            being cared for in a health facility.
- 9            (6) Criminal events, including the following:
- 10           (A) Any instance of care ordered by or provided by
- 11           someone impersonating a physician, nurse,
- 12           pharmacist, or other licensed health care
- 13           provider;
- 14           (B) The abduction of a patient of any age;
- 15           (C) The sexual assault on a patient within or on the
- 16           grounds of a health facility; and
- 17           (D) The death or significant injury of a patient or
- 18           staff member resulting from a physical assault
- 19           that occurs within or on the grounds of a
- 20           facility.



1        (7) An adverse event or series of adverse events that  
2                    cause the death or serious disability of a patient,  
3                    personnel, or visitor.

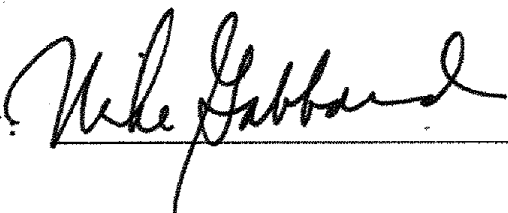
4        (b) The department shall use the information and results  
5 of the data and analysis under this section for the purposes of  
6 developing and implementing policies to reduce the occurrence of  
7 adverse events in health care facilities in the State.

8        (c) The director of health shall submit an annual report  
9 to the governor and the legislature at least twenty days prior  
10 to the convening of each regular session detailing the type and  
11 frequency of adverse events and where they occurred during the  
12 previous year. The director shall make this annual report  
13 accessible to the public on the department of health website."

14        SECTION 2. New statutory material is underscored.

15        SECTION 3. This Act shall take effect upon its approval.

16

INTRODUCED BY: 





**Report Title:**

Health Care Facilities; Adverse Events; Reporting

**Description:**

Requires department of health to collect data and submit annual reports on the number of adverse events in health care facilities in the State.

